AUG 9 2000

510(k) Summary
Special 510(k): Device Modification
S3 Cardioplegia Control Module Version 2.0
(per 21 CFR 807.92)

K002116

1. SPONSOR/APPLICANT

Stöckert Instrumente GmbH
Lilienthalallee 5-7
80939 Munich
Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
Telephone: 011 49 89 323 010
Facsimile: 011 49 89 323 4238

2. DEVICE NAME

Proprietary Name: S3 Cardioplegia Control Module Version 2.0
Common/Usual Name: Cardioplegia Control Module
Classification Names: Cardiopulmonary bypass heart-lung machine console accessory

3. PREDICATE DEVICE

S3 Cardioplegia Control Module K962320

4. INTENDED USE

The S3 Cardioplegia Control Module Version 2.0 is an accessory to the S3 Cardiopulmonary Bypass System Console that, when used in conjunction with other S3 Perfusion System modules, allows for the control and monitoring of the delivery of cardioplegia solutions during cardiopulmonary bypass procedures.

5. DEVICE DESCRIPTION

The S3 Cardioplegia Control Module Version 2.0 is a modification of the S3 Cardioplegia Control Module. Both the proposed and parent devices control and monitor the delivery of cardioplegia solution from either one or two connected S3 System pumps. The proposed S3 Cardioplegia Control Module Version 2.0 is identical in intended use and fundamental technology to the parent S3 Cardioplegia Control Module. Modifications are limited to the following:

- Introduction of a control feature to prevent the control module from being switched off or the flow ratio from being changed to manual, unless the speed(s) of the connected pump(s) is set to zero
- Expansion of the selectable flow ratios to include 12/1, 14/1, and 16/1

6. BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The S3 Cardioplegia Control Module Version 2.0 is a modification of the S3 Cardioplegia Control Module and is therefore substantially equivalent to the S3 System. This determination is based on equivalence in intended use and technological characteristics (design and operation). System modifications have been validated according to Stöckert Instrumente Design Control procedures, in compliance with the Quality Systems Regulations. Stöckert Instrumente GmbH also believes that any differences between the proposed and parent control modules are minor and raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 2000

Medical Device Consultants, Inc.
C/O Cynthia J. M. Nolte, Ph.D., RAC
Staff Consultant
49 Plain Street
North Attleboro, MA 02760

Re: K002116
S3 Cardioplegia Control Module Version 2.0
Regulatory Class: II (two)
Product Code: DTQ
Dated: July 12, 2000
Received: July 13, 2000

Dear Dr. Nolte:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002116

Device Name: S3 Cardioplegia Control Module Version 2.0

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K002116

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____